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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,902	08/11/2006	Brian Alvin Johns	PR60567USW	7724

513 7590 12/19/2008

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WASHINGTON, DC 20006-1021

EXAMINER	
O'DELL, DAVID K	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
12/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,902	JOHNS ET AL.	
	Examiner	Art Unit	
	David K. O'Dell	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-8,10-21,25-29 and 33-40* is/are pending in the application.

4a) Of the above claim(s) *20,21,28,29,35,39 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-8,10-19,25-27,33,34 and 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/22/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This application is a 371 of PCT/US05/04085 filed 02/10/2005, which claims benefit of 60/543,670 filed 02/11/2004.

Claims 5-8, 10-21, 25-29, 33-40 are pending. Claims 20-21, 28-29, 35, 39, 40 are withdrawn.

Claim Rejections/Objections Withdrawn

2. The rejections of claims under 112 1st paragraph for scope of enablement is withdrawn based upon the claim amendments and arguments. The objections to the title and the 112 2nd paragraph are withdrawn based on the amendments and the arguments of counsel.

Claim Rejections/Objections Maintained/ New Grounds of Rejection

3. The rejection of claims 5-8, 10-19, 25-27, 33, 34, 36-38 over the judicially created doctrine of obviousness type double patenting (ODP) over 11/997,786, 11/478,218, and 10/524,281 are maintained. The 10/524,281 has issued as U.S. 7,358,249. The issue fee had been paid at the time of last action and the rejection was not provisional. The examiner may be in a position to withdraw provisional rejections based on applications with a later filing date if these are the only remaining rejections, however the rejections over the '786 and '218 applications are not the only remaining rejections since the '249 patent ODP rejection is still valid and not overcome. The applicant appears to be suggesting that unexpected results have been found with the instantly claimed compounds, over those of the '249 patent. The applicant has pointed to compound 117B, yet has not pointed to comparative data for any particular compound or compounds in the '249 patent or that acquired elsewhere. Regardless, at least in a

very good portion of the claims the claims in the '249 patent and the instant case cover the same compounds and speaking of unexpected results for the same compounds is not a consideration.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5-8, 10-19, 25-27, 33, 34, 36-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11, 17-19 of copending Application No. 11/997,786. The claims overlap in scope. This is a provisional obviousness-type double patenting rejection.

Claims 5-8, 10-19, 25-27, 33, 34, 36-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5 of copending Application No. 11/478,218. The claims overlap in scope. This is a provisional obviousness-type double patenting rejection

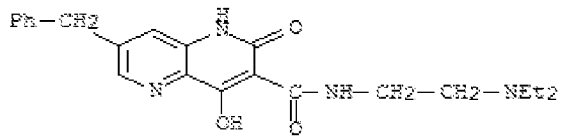
Claims 5-8, 10-19, 25-27, 33, 34, 36-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending U.S. patent 7,358,249. The claims overlap in scope. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Determination of the scope and content of the prior art and the instant claims

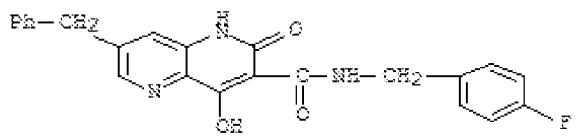
(MPEP 2141.01)

The '249 patent teaches the compounds of the instant case. Where in claim 1, Formula I, R^1 is H, R^2 is H, R^3 is alkyl substituted by $N(R^aR^b)$, where R^a and R^b are alkyl, the compounds shown below are produced:

RN 675614-21-8 CAPLUS
CN 1,8-Naphthyridine-3-carboxamide, N-[2-(diethylamino)ethyl]-1,2-dihydro-4-hydroxy-2-oxo-7-(phenylmethyl)- (CA INDEX NAME)

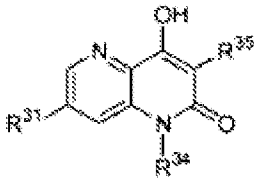


RN 675614-22-9 CAPLUS
CN 1,8-Naphthyridine-3-carboxamide, N-[(4-fluorophenyl)methyl]-1,2-dihydro-4-hydroxy-2-oxo-7-(phenylmethyl)- (CA INDEX NAME)

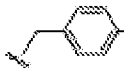
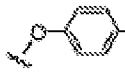


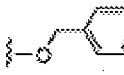
In addition these compounds have the same utility (HIV integrase inhibiton). Furhter preferred embodiments are pointed to in the specification, i.e. where R31 is 31A and R35 is various amides:

The present invention further includes the following compounds. These compounds may be synthesized in a manner similar to that of the above Examples.



The substituents of R^{31}, R^{34} and R^{35} on the above compounds are exemplified by the following substituents:

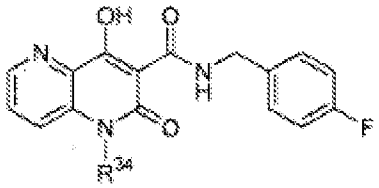
R^{31} =  (31A)  (31B)  (31C)

 (31D)  (31E)  (31F)

R^{34} = Me (34A), Et (34B), Pr (34C), COMe (34D), SO_2Me (34E)

R^{35} = COOMe (35A), COOEt (35B), COOiPr (35C), COEt (35D), $COCH_2CH_2CH_2OMe$ (35E), CONHMe (35F), CONHEt (35G), CONHCH2CH2OMe (35H)

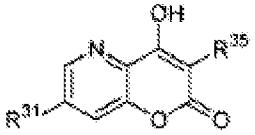
R^{34} is 34A and R^{35} is 35A. Other combinations are also shown in a similar manner.



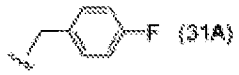
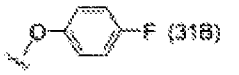
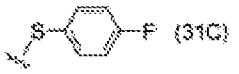
The substituent of R^{35} on the above compound includes the following:

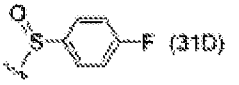
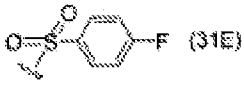
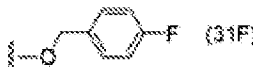
R^{34} = Me (34A), Et (34B), Pr (34C), COMe (34D), SO_2Me (34E)

The present invention includes the following compounds. These compounds may be synthesized in a manner similar to that of above Examples.



The substituents of R^{31} and R^{35} on the above compounds are exemplified by the following substituents:

R^{31} =  (31A)  (31B)  (31C)

 (31D)  (31E)  (31F)

R^{35} = COOMe (35A), COOEt (35B), COOiPr (35C), COEt (35D), $COCH_2CH_2CH_2OMe$ (35E), CONHMe (35F), CONHEt (35G), CONHCH2CH2OMe (35H)

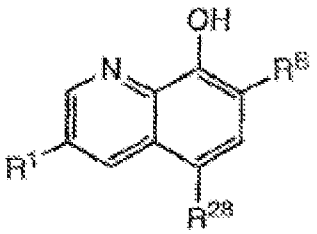
The preferable combinations of substituents (shown in the order of (R^{31}, R^{35})) involve the followings:

(31A, 35A), (31A, 35B), (31A, 35C), (31A, 35D), (31A, 35E), (31A, 35F), (31A, 35G), (31A, 35H), (31B, 35A), (31B, 35B), (31B, 35C), (31B, 35D), (31B, 35E), (31B, 35F), (31B, 35G), (31B, 35H), (31C, 35A), (31C, 35B), (31C, 35C), (31C, 35D), (31C, 35E), (31C, 35F), (31C, 35G), (31C, 35H), (31D, 35A), (31D, 35B), (31D, 35C), (31D, 35D), (31D, 35E), (31D, 35F), (31D, 35G), (31D, 35H), (31E, 35A), (31E, 35B), (31E, 35C), (31E, 35D), (31E, 35E), (31E, 35F), (31E, 35G), (31E, 35H), (31F, 35A), (31F, 35B), (31F, 35C), (31F, 35D), (31F, 35E), (31F, 35F), (31F, 35G), (31F, 35H)

For Examples: (R^{31}, R^{35}) = (31A, 35A) means a compound wherein R^{31} is 31A; and R^{35} is 35A. Other combinations are also shown in a similar manner.

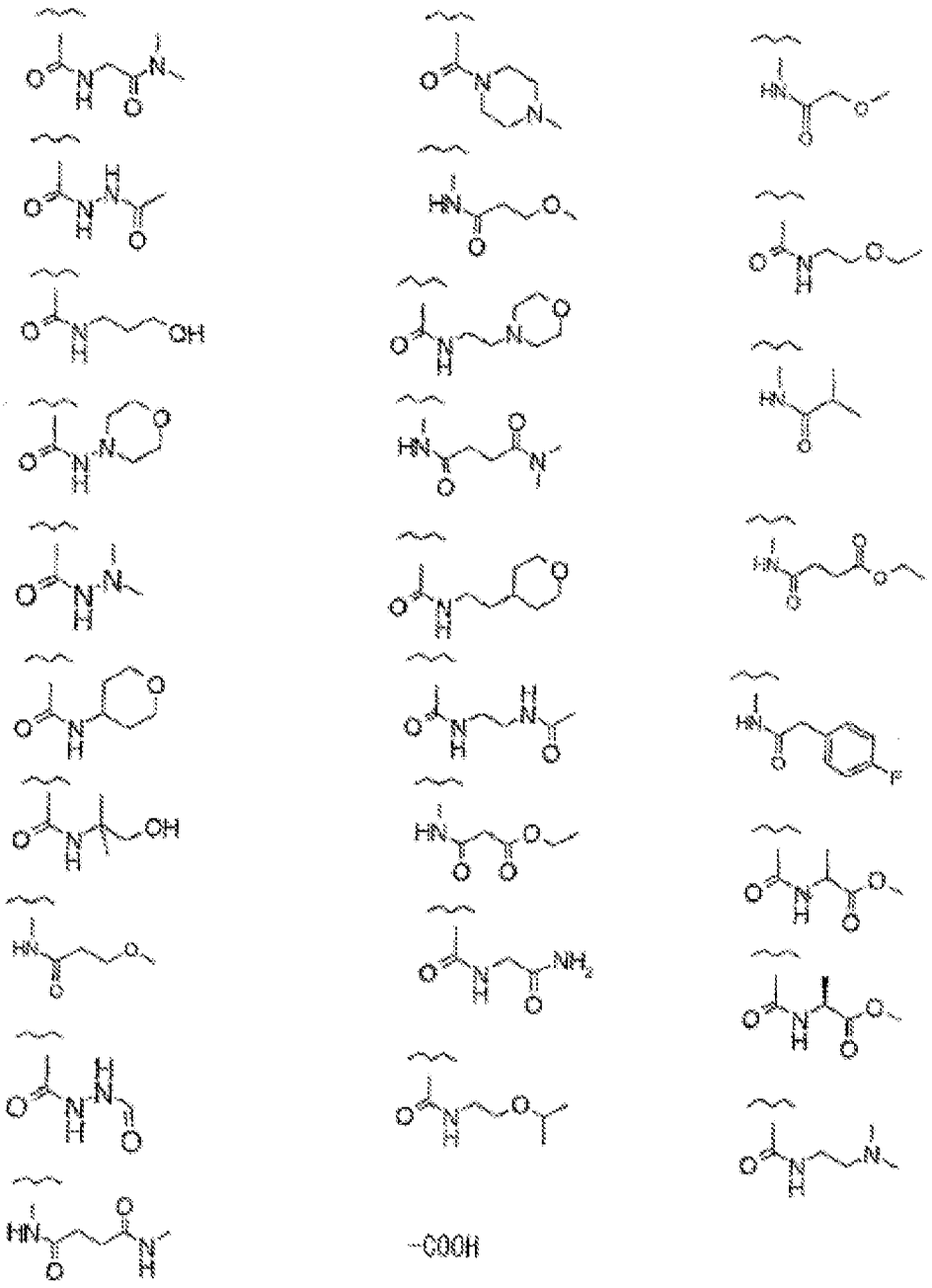
These preferred embodiments are pointed to in claim 10. This would appear to be a case of anticipation as in *In re Schauman*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978) or *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

In addition to anticipatory species, the document also provides additional evidence for the obviousness of additional claims. In particular where in the instant case R1 is halogen or hydrogen, R2 is alkyl, sulfone, ketone or hydrogen, and R3 is alkyl or alkyamino or alkylalkoxy. Moreover the substituents on the bioisosteric quinolines also disclosed in this document on pg. 20. This position is referred to as R_{28} in structure III-1 below:



(III-1)

This corresponds to the R2 position of the instant claims. The structure of the R28 groups are shown below (From pg. 21):

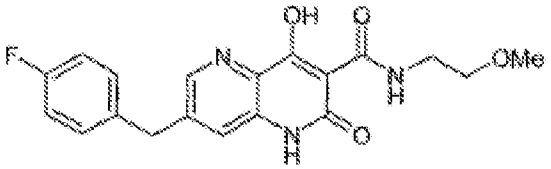


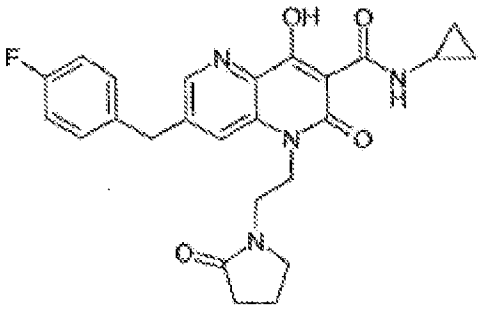
Ascertainment of the difference between the prior art and the claims

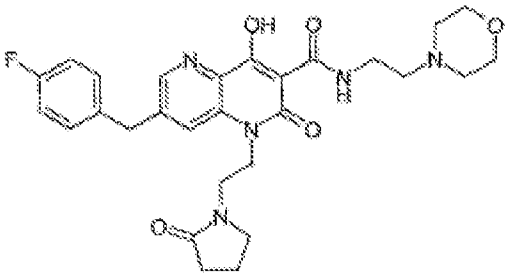
(MPEP 2141.02)

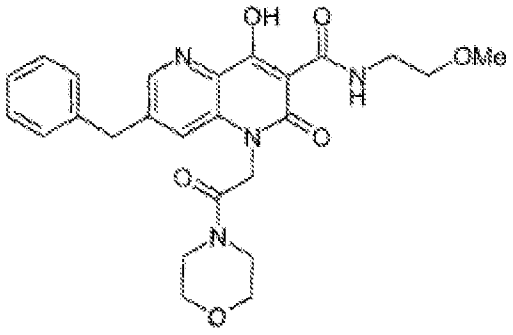
Comparing the instantly claimed preferred compounds (those with biological data), Below:

Example 2

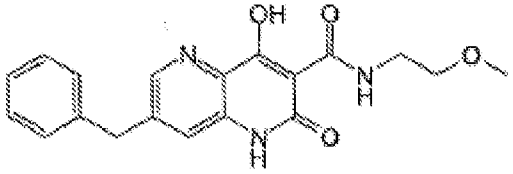


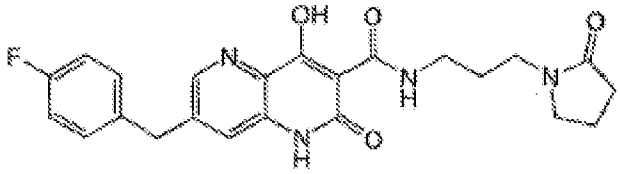


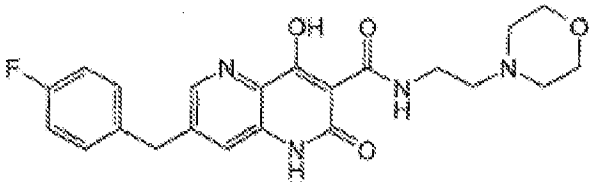


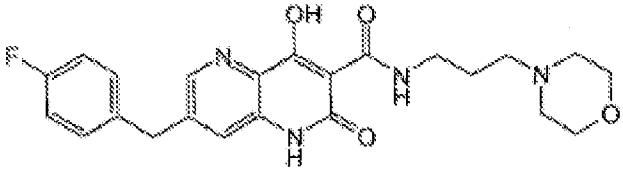


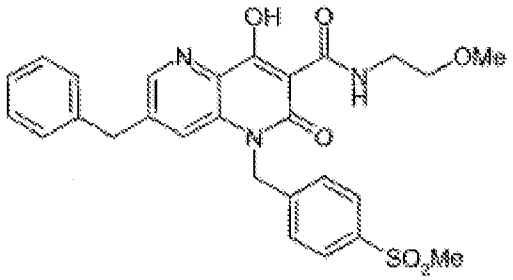
Example 17:

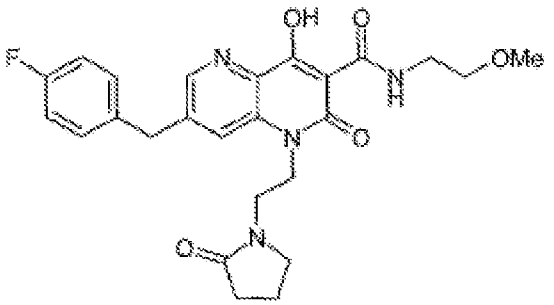




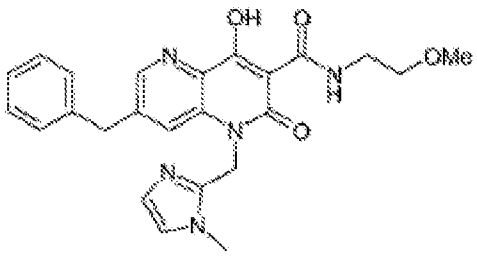




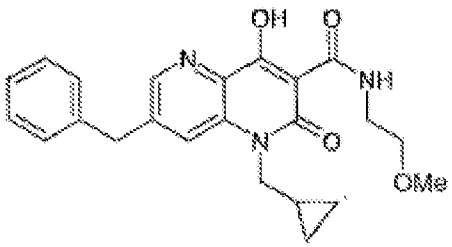




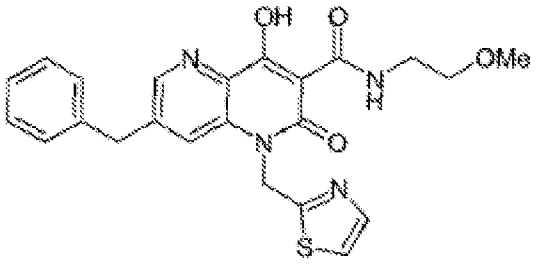
Example 50:



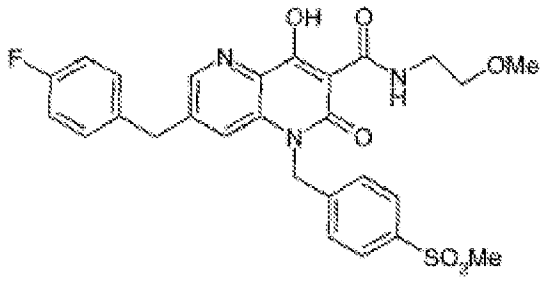
Example 54:



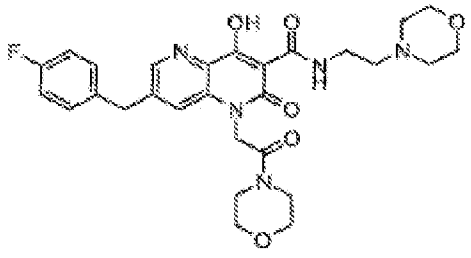
Example 62:



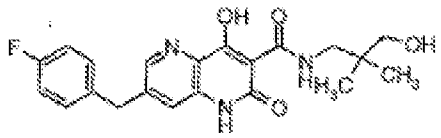
Example 64:



Example 83:



Example 85:



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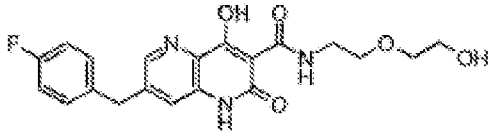

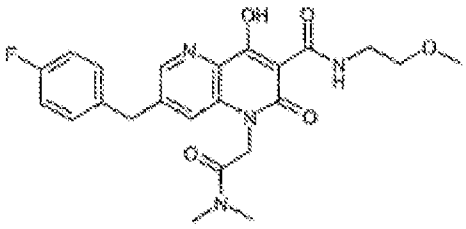

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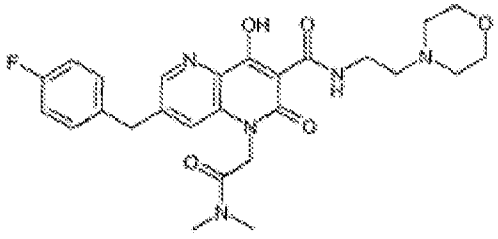
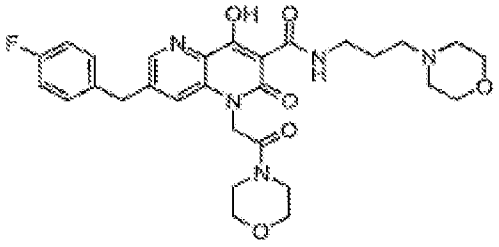
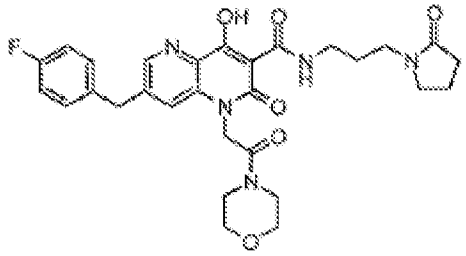
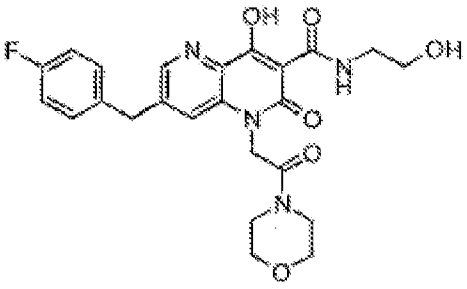




Example 94:





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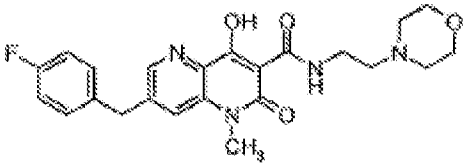

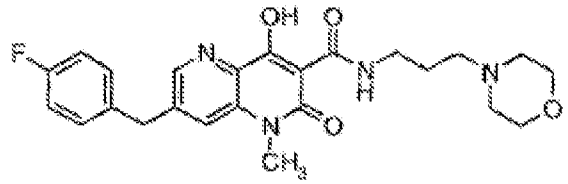

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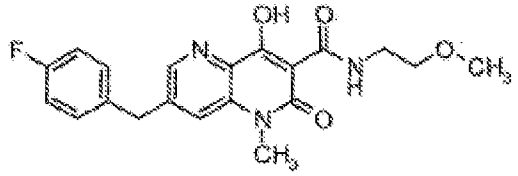
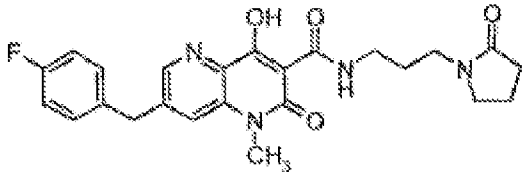
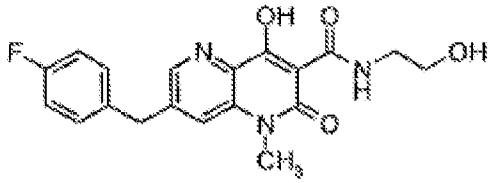


Example 99:



Example 101:



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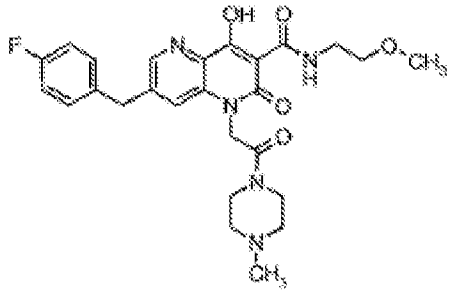

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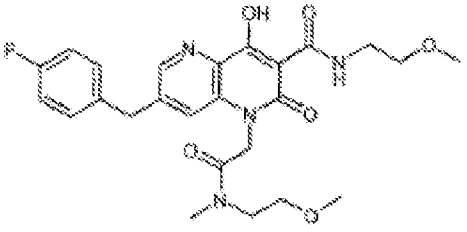
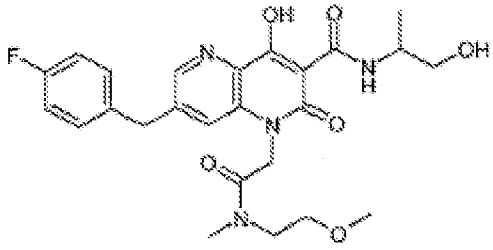
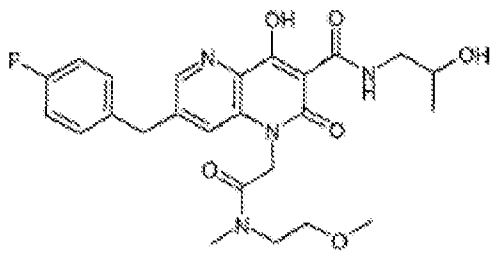
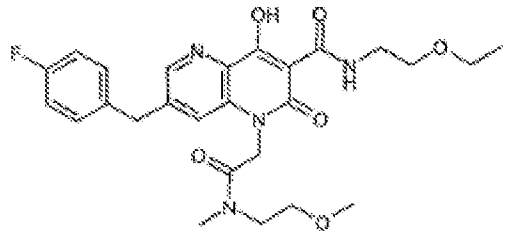




Example 106:



Example 107:



It is clear that all these substitutions were within the teaching of the claimed invention in the '249 patent, in particular when the various preferred moieties are considered (i.e. claim 10 of the '249 patent)

Finding of prima facie obviousness

Rational and Motivation

(MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make compounds of the copending to produce the instant invention. The experienced Ph.D. synthetic organic chemist, who would make Applicants' compounds, would be motivated to prepare these compounds on the expectation that anticipatory compounds or analogues falling within the general teaching would have similar properties and upon the routine nature of such experimentation in the art of medicinal chemistry.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

One of ordinary skill is also one of "ordinary creativity, not an automaton". See Leapfrog Enterprises Inc. v. Fisher-Price. and Mattel Inc. UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT "An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 550 U.S. , 2007 U.S. LEXIS 4745, 2007 WL 1237837, at 12 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell whose telephone number is (571)272-9071. The examiner can normally be reached on Mon-Fri 7:30 A.M.-5:00 P.M EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D.K.O.

/Rita J. Desai/

Primary Examiner, Art Unit 1625